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TITLE:
Treatment of Early Post-op Wound Infection after Internal Fixation

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Postoperative infection is one of the most prevalent and challenging complications faced by orthopaedic surgeons and patients in both the military and civilian populations. The wounds are contaminated or colonized at the time of injury, during the course of therapy, or both. Infection is always a possibility with any surgical intervention, particularly in the setting of orthopaedic trauma where multiple factors make the prevention and treatment of these infections very complicated.

As of October 1, 2017, a total of 1624 patients have been screened for eligibility, and of these, 731 (45%) were eligible. Of the 731 eligible patients, 173 (24% of eligible) were consented and enrolled into the RCT; 117 (16% of eligible) were consented and enrolled into the observational arm. We have now reached 65.5% of our total enrollment. One hundred and sixty-three patients have completed the study.

15. SUBJECT TERMS
PO, IV, Antibiotics, plate, fixation, infection

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Annual Report: "Treatment of Early Post-Op Wound Infection after Internal Fixation"
Sept. 15, 2016 - Sept. 14, 2017

Introduction:
Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to investigate the efficacy of oral (per os, (PO)) antibiotic therapy versus intravenous (IV) antibiotics in the treatment of acute infection after fixation of fractures or fusion of joints.
Study Specific Aim # 1: To evaluate the effect of treatment of post-op wound infection in bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks.
Study Specific Aim # 2: To build and validate a risk prediction model for failure of treatment of early post-op wound infections after fixation of fractures and joint fusions.

Body:
During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to recruitment and enrollment into the study. As of October 1, 2017, a total of 1624 patients have been screened for eligibility, and of these, 731 were eligible. Of the 731 eligible patients, 173 (24% of eligible) were consented and enrolled into the RCT; 117 (16% of eligible) were consented and enrolled into the observational arm. We have now reached 65.5% of our total enrollment. One hundred and sixty-three patients have completed the study.

Task 1	Months 1-6	Completed
Task 2	Months 6-72	Completed
Task 3	Months 12-84	Enrollment – in progress
Task 4	Months 48-84	Complete Follow up visits- in progress
Task 5	Months 84-96	Conduct analysis and final report- in progress

NEXT STEPS:

- Continue enrollment through September 2018.
- Complete follow up visits by September 2019.
- Begin data analysis once we reach 50% of enrollment in the RCT goal as per protocol
- Encourage each site to enroll 6 patients over the next 12 months to meet enrollment goals
- Develop reports related to project deliverables for Consortium

Key Research Accomplishments:

- We have reached 65.5% of our enrollment goals
- 163 patients have completed the study
- The implementation of the observation arm has increased our enrollment rate.

Reportable Outcomes:

There were 35 serious adverse events (SAEs) reported during this reporting period. One SAE was due to death. Twenty-three events were related to abnormal laboratory results and each determined by the medical monitor to be unrelated to study participation. Three patients experienced worsening/new infections. Two where due to pain and swelling related to patient injury. The remaining four consisted of allergic reaction to vancomycin, DVT, re-fracturing of uninjured limb, acute pancreatitis, hypokalemia, and hypotension.

The medical monitor reviewed all SAEs and determined that no further action was required.

Conclusion: None

References:

None

Appendices:

Quad Chart

Treatment of Early Post-Op Wound Infection after Internal Fixation

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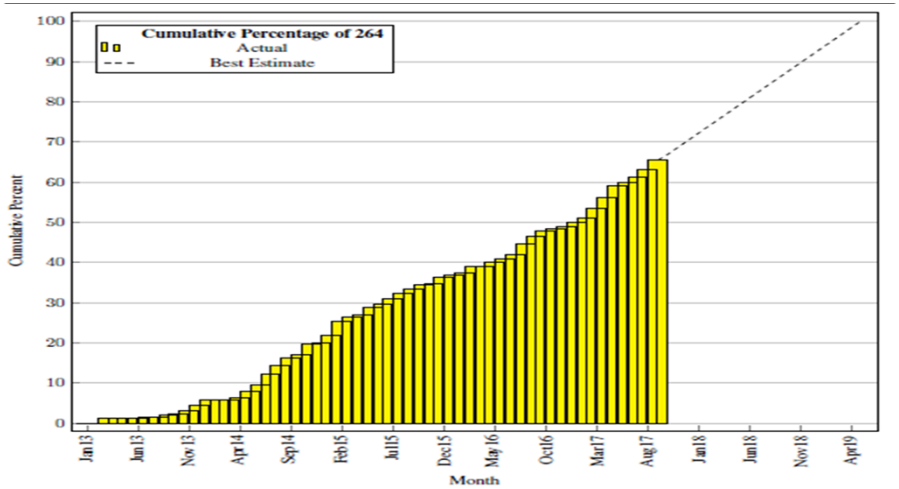
PI: William Obremskey, MD MPH **Org:** Vanderbilt University Medical Center **Award Amount:**$2,972,205

Study/Product Aim(s)

- PO antibiotics efficacy equal to IV antibiotics
- PO and IV antibiotic bioavailability is similar
- Development high level evidence to inform clinician choices regarding post operative infections and potentially inform practice changes

Approach

We will compare PO vs IV antibiotics in patients with infections of internal fixation of fractures/ fusions. Patient will be monitored for Infection recurrence, amputation, line sepsis and other complications.



We have completed 65.5% of our total RCT enrollment with 173 patient in RCT. Also 117 are enrolled in an observational. 163 patients have completed study.

Timeline and Cost

Activities / CY	13-14	15-16	17-18	18-19
Active enrollment				
Active Follow- up				
Data Analysis				
Manuscript and Final Report				
Estimated Budget ($K)	**$650**	**$600**	**$600**	**$600**

Updated: (10-1-17)

Goals/Milestones CY11 Goal – Finalize Study Protocol
☑ Train and Certify Staff
CY12 Goals – IRB Approval
☑ Obtain DoD and local IRB approvals
CY13 Goal – Initiate Patient Enrollment
☑ Data entry via REDCap, routine training of sites
CY14 Goal – Continue Enrollment, Initiate Follow-up
☑ Quality reports to sites with request for missing data
CY15 Goal – Continue Enrollment and Follow -up
☑ Quality reports to sites with request for missing data
CY16Goal – Continue Enrollment and Follow -up
☑ Quality reports to sites with request for missing data
CY17Goal – Continue Enrollment
CY18 Goal – Complete Enrollment
CY19 Goal – Complete Follow-Up
☐Finish data cleaning and analysis, final report

Budget Expenditure to Date
Projected Expenditure:
Actual Expenditure: